UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,804	06/30/2003	Nobuko Yamamoto	03500.015716.1	2559

5514 7590 05/16/2007
FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
BAUSCH, SARAE L	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,804	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/28/2007 has been entered.

1. Currently, claims 74-77 are pending in the instant application. Claims 1-73 have been cancelled and 77 has been added. The previous rejections under 35 U.S.C. 112(2) is withdrawn in view of the amendments. The following rejections are either newly presented, or are reiterated from the previous office action. **This action is a Non-Final.**

Claim Rejections - 35 USC § 112- New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 74-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was previously presented in the office action mailed 10/31/2006 and has been rewritten to address the amendment to claims 74-76 and newly added claim 77.

The currently amended claims 74-76 with the recitation of "side length from 500 μm to 6 mm" and the newly added claim 77 with the recitation of "side length of the square section is 2 mm" is not supported in the specification and raises the issue of new matter. The specification does not teach a range for the side of a sequare. The specificaiton teaches a matrices with a region of 1mm by 1mm (see substitute specificaiton page 13, line 6), a density of matrices that is a 500 μm square (see page 15, line 20), thickness of the matrix is 1 to 20 μm (see page 19, line 35), spots that are 500, 100, and 20 μm (see page 33, line 25-29), a 6 mm and 1.2 mm square section (see page 34, lines 11-15), and a glass substrate of 60 mm x 50 mm with a well that is 1 mm x 1mm square. The specification provides no indication of the criticality of the amended range and provides no example of any actual assay which demonstrates side lenghts of a square or substrate in the amended range. The specificaiton does not teach a 2mm side length of a square section. There is no support in the specification to use a side length of 500 μm to 6 mm or a side length of 2mm that are arranged in a matrix form having no walls partitioning the sections. As discussed in MPEP 2163.05, section III, with respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

Newly added claims 74-76 with the recitation "having no walls partitioning the sections" is not supported in the specification and raises the issue of new matter. The specification teaches a detection substrate with sections separated by wells (walls) of the frame structure matrix patterns (see page 28, line 35-36). The specificaiton discloses the use of a hydrophobic wall on the detection substrate (See page 29, lines 1-5 and page 41, lines 10-15).. The specification further exemplifies the rectangular sections are each spatially isolated by matrix components that with surrounding walls (see page 31, line 13-16). The specificiaotn does not disclose the use of a substrate that has square sections that are arranged in a mtric form on a solid substrate that has no walls partitioning the sections. There is no support in the specification to use a substrate without walls. The specification is limited to a substrate that is made of walls and wells.

Response to Arguments

4. The response asserts on page 4 that the comments by the examiner are not well-understood. The response asserts that the size of the square discussed in the specification is its side length as there are no other plausible explanation for the term "square size" given the recited units. This response has been thoroughly reviewed but not found persuasive. The specification teaches a matrices with a region of 1mm by 1mm (see substitute specificaiton page 13, line 6), a density of matrices that is a 500 μm square (see page 15, line 20), thickness of the matrix is 1 to 20 μm (see page 19, line 35), spots that are 500, 100, and 20 μm (see page 33, line 25-29), a 6 mm and 1.2 mm square section (see page 34, lines 11-15), and a glass substrate of 60 mm x 50 mm with a well that is 1 mm x 1mm square. The specification provides no indication of the criticality of the amended range and provides no example of any actual assay which demonstrates side lenghts of a square or substrate in the amended range. The specification does

not teach square "sections" having a side length of 500 microns to 6mm. Furthermore, the support for a 500 um is found only in the density of the matrices as well as the spot, which does not describe a side length of a square.

The response asserts that with respect to the absence of walls partitioning sections, example 5 indicates that these walls are not present. The response asserts that the method for forming the array is disclosed and this clearly does not result in the formation of partitioning walls. This response has been thoroughly reviewed but not found persuasive, as stated previously, example 5 does not disclose an array that has a plurality of square sections with a side length of 500 μm to 6 mm and arranged in a matrix on solid substrate having no walls. Example 5 discloses a 2 mm square (no teachings of a plurality of squares) in which 64 DNAs were printed (see page 64, lines 12-16). Example 5 is silent with regard to the presence of walls on the substrate and does not describe the partitions between the squares. However, the specification very clearly teaches a detection substrate with hydrophobic wall on the detection substrate, see page 29, lines 1-5 and page 41, lines 10-15 and therefore the lack of teaching of a walls on substrate in example 5 does not provide support for a plurality of square sections with a side length of 500 μm to 6 mm in length which are arranged in matrix form having no walls partitioning the sections.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 74-75 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US Patent 5807522 Sep. 1998).

With regard to claims 74-75, Brown et al. teach a method of detecting differential expression of each of a plurality of genes in a first cell type with respect to expression of the same genes in a second cell type (see column 4, lines 52-59). Brown et al. teach mixtures of labeled cDNA from the two cell types is added to an array of polynucleotides representing a plurality of known genes (component from at least two liquid test samples) (see column 4, lines 60-63). Brown et al. teach the array is examined by fluorescence to determine the relative expression of known genes in the two cell types by each spot (determining whether the object component is contained in each of the two liquid test samples) (see column 4, lines 64-67 and column 5, lines 1-5). Brown et al. spotting polynucleotides of about 50 bp on the array surface and a small volume of labeled DNA probe mixture (at least two liquid test samples) in a standard hybridization solution is loaded onto each cell and incubation at appropriate temperatures for hybridization by reaction with detection reagents and analyzed using calorimetric, radioactive, or fluorescent detection (see column 13, lines 10-46). Brown et al. teach 100 DNA fragments representing all known mutations of a given gene fabricated on an array (fixing plural types of oligonucleotides having known base sequence different from one another). Brown et al. teach an array of regions on a solid support comprising a two dimensional array with discrete regions having a finite area (see column 6, lines 29-32) and teach the 96 cell array is about 1 to 30 mm in width and 1 to 50 mm in length (claim 77) (see column 11, lines 62-67). Brown et al. teach the

array is formed in a plurality of analyte-specific reagent regions, each region may include a different analyte-specific reagent and teach the 96 microarrays assayed with 96 patient samples are incubated, rinsed, detected, and analyzed using standard calorimetric, radioactive, or fluorescent detection and teaches the process can be reversed where the patient or organism's DNA is immobilized as the array elements and each array is hybridized with a different mutated allele or genetic marker (claim 75) (see column 15, lines 18-51).

7. Claims 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Southern et al. (US Patent 5700637 published Dec. 23 1997).

With regard to claim 74-76, Southern et al. teach an apparatus and method for analyzing a polynucleotide sequence of a known or unknown sequence. Southern et al. teach an apparatus comprising a support and attached to the surface a complete set of oligonucleotides of chosen lengths occupying separate cells and being capable of taking part in hybridization reactions (object component capable of binding to the oligonucleotide) (see column 1, lines 35-47). Southern et al. teach the use of a support by applying labeled material under hybridization conditions to the array to observe the location of the label on the surface associated with particular members of the oligonucleotides (see column 1, lines 52-60). Southern et al. teach preparing a substrate with a plurality of regions (squares) and teaches stripes that 1mm long (side length) (see column 14, lines 48-50). Southern et al. teach the spots can be laid down with a low cost ink jet printer (see column 6, lines 53-56) (claim 76). Southern et al. teach that adding a plurality of oligonucleotides with two different bases in a rectangular patch on the substrate (fixing plural types of oligonucleotides having known base sequences different from one another and present at a uniform surface density in each section) (claim 75) (see column 10, lines 1-6 and

example 3). Southern et al. teach preparing clinical samples of three different DNA samples and applying these probes in liquid sample to the surface carrying six oligonucleotide strips and detecting the hybridization signal (detecting whether a complex formed between the oligonucleotide and object component) (see column 12, lines 1-23, example 6).

Response to Arguments

8. With regard to the rejection of Southern et al, the response asserts that the amendment after final addressed where Southern teaches partitioning walls. The response asserts that Southern is directed to a conventional testing method in which probes are placed in wells and then the material to be analyzed is loaded into the wells and thus Southern discloses wells. As these wells are necessarily separated by walls. This response has been thoroughly reviewed but not found persuasive. In the amendment after final, the response did not specifically point out where in the reference of Southern et al. the walls are disclosed, additionally in the instant response, the response again did not specifically point out where in the reference the walls are taught. Southern et al. does not disclose walls, however if applicant believes that Southern et al. does disclose walls, it is suggested that applicant should specifically address and cite where in the reference by Southern et al. the walls are disclosed. Therefore, Southern et al. anticipates the claims invention.

9. The response asserts on page 6, 3rd paragraph that Brown teaches separating each region by grid lines which extend beyond the surface and these grid lines are taught at column 12, lines 1-36 and figure 11. This response has been thoroughly reviewed but not found persuasive. As stated in the last office action, Brown et al. does not teach partitioning walls. Brown et al. teach an array with a plurality of analyte-specific reagents regions with diameter region and spacing

and teach the support is treated to evaporate the liquid droplet from each region leaving an array of dried relatively flat regions (see column 9, lines 30-45). Brown et al. further teach grid patterns with grid lines (see column 12, lines 1-36) but does not teach the grid lines, grid patterns, or array are separated by a partitioning wall. Therefore, Brown et al. anticipated the claimed invention.

10. For these reasons, and the reasons made of record in the previous office actions, the rejections are maintained.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Sarae Bausch
Examiner
Art Unit 1634